IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, *et al.*, Plaintiffs, vs. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 8:20-cv-1320-TDC

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs, a coalition of abortion providers and abortion advocacy organizations, ask this Court to be the first court to hold unconstitutional critical in-person dispensing requirements for a drug with serious health risks that have been in place for two decades and under four administrations. In 2000, FDA approved Mifeprex[1] (the first FDA approved drug for non-surgical abortions) with certain restrictions related to the drug's prescribing and dispensing, including that the drug be dispensed only in certain healthcare settings, by or under the supervision of a certified prescriber ("in-person dispensing requirement"). FDA put these restrictions in place to help mitigate the serious risks associated with Mifeprex, which include incomplete abortion and serious bleeding requiring surgical intervention in up to seven percent of women who take the drug. *See* Compl. Ex. 1 (Dkt. No. 1-3) at 17.

Plaintiffs urge the Court to sweep away the scientific judgment of the Food and Drug Administration ("FDA") regarding these important safeguards. Plaintiffs insist that these requirements lead to medically unnecessary travel and visits to healthcare facilities, which allegedly pose a significant threat of COVID-19 transmission and illness and thereby supposedly violate plaintiffs' due process and equal protection rights. Pls.' Am. & Corr. Mem. in Supp. of Mot. For Prel. Inj. at 35 (Dkt. No. 12) ("PI Br."). The Court should reject plaintiffs' request to substitute its judgment for FDA's.

To begin, plaintiffs lack standing because their alleged harm—that patients might "contract[] a life-threatening illness" if they leave their homes—is speculative. PI Br. at 26. Furthermore, Mifeprex prescribers are not entitled to assert the rights of patients. They fail to show that they have the sort of close relationship with patients necessary to establish third-party

[1] The use of "Mifeprex" in this brief refers to the brand-name and generic versions of the drug.

standing. Indeed, the entire point of this suit is to *reduce* plaintiffs' relationship with patients to electronic interactions and mail.

Even if plaintiffs could surmount these hurdles, they still have not established a likelihood of success on their claims. Their due process claim—that the in-person dispensing requirement imposes an undue burden on their patients' ability to obtain an abortion— fails for numerous reasons, including that there is no substantive due process right to use this particular drug to obtain an abortion. FDA did not even approve Mifeprex until 2000, and there could have been no claim prior to that date that its absence imposed a substantial obstacle to obtaining an abortion. Even setting that fundamental problem aside, plaintiffs have not shown that adhering to the in-person dispensing requirement during the COVID-19 pandemic poses a substantial obstacle to a large fraction of women seeking an abortion, much less that it is invalid in all circumstances. The drug is approved for use only through the first ten weeks of pregnancy and thus is not approved for use for many women seeking a pre-viability abortion. *See* Compl. Ex. 1 at 17. Traveling to a clinic to receive Mifeprex is also unquestionably less burdensome than other commonly used methods of obtaining an abortion, such as an in-office surgical procedure. In any event, FDA's determination that the in-person dispensing requirement is necessary to ensure Mifeprex's safe use is a reasoned scientific judgment based on the agency's expert evaluation of the serious health risks associated with the drug's use and is entitled to deference. Plaintiffs' equal protection claim likewise fails because the in-person dispensing requirement is rationally related to patient safety and there is a rational basis for keeping the requirement in place during the pandemic.

Plaintiffs also cannot satisfy the remaining preliminary injunction factors. Plaintiffs' asserted injury—increased risk of COVID-19 exposure— is too speculative to establish an

Article III injury, much less irreparable harm. Plaintiffs emphasize the risk of COVID-19 to the population at large, but the risk is far lower for women under the age of 50—the demographic group that uses Mifeprex. Plaintiffs' requested relief is also contrary to the public interest in ensuring patient safety. Finally, plaintiffs' asserted injury does not warrant nationwide relief because plaintiffs, who have declined to seek class certification, are not in a position to represent all similarly situated Mifeprex prescribers, let alone their potential patients.

BACKGROUND

I. Statutory and Regulatory Background

Under the Federal Food, Drug, and Cosmetic Act (FDCA), a sponsor must apply for and secure FDA approval to market a "new drug." 21 U.S.C. § 355(a). FDA approves two general categories of such applications: a new drug application (NDA) for what are commonly referred to as "brand-name drugs," and an abbreviated new drug application for what are commonly referred to as "generic" versions of brand-name drugs. *See* 21 U.S.C. §§ 355(a), (b), (j). FDA may approve an NDA only if it determines that the drug is safe and effective for use in accordance with its proposed indications and labeling. *See* 21 C.F.R. § 314.50(a)(1); 21 U.S.C. § 355(b)(1)(A), (F); 21 U.S.C. § 355(d).

FDA may require a Risk Evaluation and Mitigation Strategy (REMS) for a drug if the agency determines that the REMS "is necessary to ensure that the benefits of the drug outweigh the risks of the drug." *See* 21 U.S.C. § 355-1(a). A REMS may include certain Elements to Assure Safe Use (ETASU), such as a requirement that a drug's prescribers have particular training or experience, that a drug be dispensed only in certain healthcare settings, or that a drug be dispensed only after documentation of safe use conditions is provided. *See* 21 U.S.C. § 355-1(f)(A). Once FDA approves a drug with a REMS, the drug sponsor later may seek to modify the REMS through submission of a supplemental new drug application (sNDA). *See* 21 U.S.C. §

355-1(g)(4). FDA does not approve modifications to a drug's REMS absent an adequate rationale, including data to support the proposed changes. *See, e.g.*, Defs.' Ex. 10 at 12.

II. Factual Background

On September 28, 2000, FDA approved an NDA for Mifeprex, authorizing the drug's use in conjunction with another drug (misoprostol) to terminate intrauterine pregnancy through the seventh week of pregnancy. Defs.' Ex. 11 at 0223. Mifeprex was the first drug approved for non-surgical abortion. *See id.*

In approving Mifeprex, FDA recognized that the drug carries serious risks, including incomplete abortion or serious bleeding that may require surgical intervention in up to seven percent of patients and that can cause maternal death. Compl. Ex. 1 at 17. To mitigate these risks, FDA placed certain restrictions on the dispensing and distribution of Mifeprex, including, but not limited to, the in-person dispensing requirement challenged here, and a requirement that Mifeprex be prescribed only by qualified healthcare providers who certify that they have the ability to accurately date pregnancies and diagnose ectopic pregnancies. Defs.' Ex. 11 at 0228; Defs.' Ex. 12 at 0016. Mifeprex is contraindicated in ectopic pregnancies, and use beyond the gestational date in the approved labeling increases the risk of incomplete abortion and serious, or even fatal, bleeding. Compl. Ex. 1 at 4-5.

FDA has maintained the restrictions initially established as part of Mifeprex's approval largely without change. In 2007, the restrictions were "deemed . . . an approved risk evaluation and mitigation strategy" (*i.e.*, a REMS) under Section 909(b)(1) of the newly enacted Food and Drug Administration Amendments Act. Defs.' Ex. 13 at 0232. In 2011, FDA affirmatively approved the Mifeprex REMS with ETASU, keeping in place the originally approved restrictions on the basis that they remained necessary to mitigate serious risks associated with the drug's use. *See id.* at 0232-36. In 2013, FDA conducted a full review of the Mifeprex REMS and reaffirmed

that "[t]he Mifeprex REMS provides the foundation to ensure the implementation of safe use conditions with Mifeprex use." Defs.' Ex. 14 at 0344.

In 2016, FDA conducted another full review of the Mifeprex REMS in response to an sNDA submitted by Mifeprex's sponsor. After a careful review of the sNDA, FDA approved certain changes that the drug sponsor proposed, with some modifications, concluding that the proposed alterations were supported by appropriate data and information. Defs.' Ex. 15 at 0464-70. These changes included eliminating the requirement that patients take Mifeprex at their provider's office, which FDA approved eliminating because the data on home use showed no significant difference in patient safety; extending the gestational period of approved use from seven to ten weeks; allowing certain nonphysicians to prescribe the drug if they meet the certification requirements; and reducing restrictions on follow-up visits. Defs.' Exs. 16 at 0414-15; Ex. 17 at 0728. Notably, however, the drug sponsor did not request—and FDA did not decide—to eliminate or modify the requirement that Mifeprex be dispensed only by a certified prescriber in certain healthcare settings. Defs.' Ex. 16 at 0414-15. FDA maintained this requirement based on the conclusion that it remained necessary to assure safe use because the drug's safety profile had "not substantially changed." Defs.' Ex. 18 at 0681. This conclusion was based on a clinical review that identified thousands of adverse events with Mifeprex between 2000 and 2014 involving hundreds of hospitalizations, transfusions, and infections. Defs.' Ex. 19 at 0610.

During both the 2013 and 2016 reviews, FDA articulated several reasoned explanations for the in-person dispensing requirement. *See* Defs.' Exs. 14, 16. FDA determined, based on its experience and scientific expertise, that limiting dispensing of Mifeprex to specified healthcare settings allowed FDA to ensure that patients are properly counseled at the time they receive the

drug about the serious complications associated with Mifeprex, which is vital to ensuring patient safety. *See* Defs.' Ex. 14 at 0356-57. Dispensing the drug in broader settings, such as through retail or mail-order pharmacies, might also expose patients to unnecessary and increased risks because patients might not receive proper counseling at the time they receive the drug about the serious complications associated with Mifeprex or what to do if they experience an adverse event. *Id.*

FDA also determined that the in-person dispensing requirement remained necessary to ensure patient safety by reducing delays in initiating the abortion process. Under the requirement, patients receive Mifeprex directly from the prescriber, which avoids potential patient delay in filling the prescription and removes the additional step of having to pick up the drug from a pharmacy, which may or may not stock Mifeprex, or having to wait for the drug to arrive in the mail. *See* Defs.' Ex. 14 at 0356-57. Given the importance of timely use of Mifeprex following its dispensing, the in-person dispensing requirement plays a key role in mitigating risks associated with the drug's use. *See id.*

On April 11, 2019, in conjunction with its approval of an abbreviated new drug application for a generic version of Mifeprex, FDA established a single, shared-system REMS for both Mifeprex and its generic called the Mifepristone REMS Program. *See* Defs.' Ex. 20 at 1; Ex. 21 at 1-3.

III. Procedural Posture

On April 20, 2020, plaintiff American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine sent a letter to FDA asking the agency not to enforce Mifeprex's in-person dispensing requirement during the COVID-19 pandemic. *See* Compl. Ex. 5. On April 28, 2020, plaintiffs ACOG and New York State Academy of Family Physicians (NYSAFP), along with several other professional associations and institutions, sent a

similar letter to FDA. *See* Compl. Ex. 6. On May 27, 2020, plaintiffs filed this suit, which raises due-process and equal-protection challenges to FDA's enforcement of Mifeprex's in-person dispensing requirement during the pandemic. Plaintiffs simultaneously moved for a preliminary injunction.

STANDARD OF REVIEW

To obtain a preliminary injunction, plaintiffs must make a "clear showing" of each of the following four factors: (1) likelihood of success on the merits; (2) irreparable harm in the absence of preliminary injunctive relief; (3) that the balance of equities tips in favor of the moving party; and (4) that the public interest favors the requested relief. *Winter v. NRDC*, 555 U.S. 7, 20 (2008). "Ordinarily, preliminary injunctions are issued to protect the status quo and to prevent irreparable harm during the pendency of a lawsuit ultimately to preserve the court's ability to render a meaningful judgment on the merits." *See Perry v. Judd*, 471 F. App'x 219, 223 (4th Cir. 2012). Plaintiffs here, however, do not seek to *maintain* the status quo. Instead, they want to *change* the status quo by overturning an FDA requirement that has been in place for decades. *See Taylor v. Freeman*, 34 F.3d 266, 270 n.2 (4th Cir. 1994). When a plaintiff seeks this sort of extraordinary and disfavored relief, courts apply a heightened standard of review. *See Pashby v. Delia*, 709 F.3d 307, 319-20 (4th Cir. 2013).

ARGUMENT

I. Plaintiffs Have Not Established a Likelihood of Success on the Merits

A. Plaintiffs Lack Standing

1. The Alleged Injury to Potential Patients is Speculative

Plaintiffs fail to allege a sufficiently imminent threat of injury to establish standing under Article III. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Plaintiffs claim that Mifeprex's in-person dispensing requirement "forces patients to incur the unnecessary risk of

contracting a life-threatening illness." PI Br. at 26. But the mere threat of potential future harm is insufficient for standing. Plaintiffs, instead, must identify an injury that is both "palpable and imminent." *South Carolina v. United States*, 912 F.3d 720, 726 (4th Cir. 2019). Plaintiffs come nowhere close to doing so here. That is because a series of speculative events would have to transpire before the alleged injury—"contracting a life-threatening illness"—could occur.

First, a potential patient would have to choose to abort her pregnancy via Mifeprex. Plaintiffs have not identified any individual among their members who is likely to do so. *Second*, that individual would have to be exposed to an environment in which the virus were present and transmittable. Traveling to a clinic presents no higher risk than many other activities outside the home. And, as the CDC has made clear, there are many precautions healthcare providers can take to reduce the risk of infecting patients with COVID-19. *See, e.g.*, CDC, *Infection Control Basics*, https://www.cdc.gov/infectioncontrol/basics/index.html (last accessed June 9, 2020). *Third*, even for those individuals exposed to the virus, the "immediate risk of becoming seriously ill from the virus that causes COVID-19 is thought to be low." CDC, *Stop the Spread of Rumors*, https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/share-facts.html (last accessed June 9, 2020). The risk is further reduced for younger individuals—the precise demographic of those taking Mifeprex. *See* CDC, *People Who are at Higher Risk for Severe Illness*, https://www.cdc.gov/coronavirus/ 2019-ncov/need-extra-precautions/people-at-higher-risk.html (last accessed June 9, 2020). Indeed, the CDC estimates that the fatality rate among individuals under 50 years of age who display symptoms is only 0.05%—and the CDC further estimates that 35% of infected individuals never even exhibit symptoms. *See* CDC, *COVID-19 Pandemic Planning Scenarios*, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html (last accessed June 9, 2020). That is far short of the likelihood

of injury that the Fourth Circuit has rejected as insufficient elsewhere. *See, e.g.*, *Beck*, 848 F.3d at 268 (33% risk of identity theft fell "far short of establishing a 'substantial risk' of harm" necessary to establish standing).

2. The Plaintiff-Prescribers Lack Third-Party Standing

Even if a potential *patient* could satisfy Article III's requirements, there is no such plaintiff here. Rather, the plaintiffs in this action are a coalition of abortion providers and abortion advocacy organizations who seek to challenge regulatory requirements applicable to one set of third parties (drug sponsors) on the ground that those requirements violate the rights of another set of third parties (patients who seek medical abortions). But plaintiffs provide no explanation as to why they have third-party standing to challenge a regulatory requirement imposed on drug sponsors. And they fail to meet the ordinary standard for asserting the rights of their third-party patients, which requires plaintiffs to demonstrate both a close relationship with their patients and that their patients are hindered from filing suit on their own. *See Kowalski v. Tesmer*, 543 U.S. 125, 130 (2004). Plaintiffs allege only brief interactions with patients who seek a prescription for Mifeprex. *See* Compl. ¶ 9 (Dkt. No. 1). That makes this case meaningfully different from others where doctors performing surgical abortions have pressed claims on behalf of their patients. *See, e.g.*, *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (4th Cir. 2000). And plaintiffs provide no reason to think that their patients are hindered from vindicating their own abortion rights—particularly in light of the many cases prospective abortion patients themselves have brought in recent decades. *See Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2323 n.1 (2016) (Thomas, J., dissenting) (collecting cases).

Nor are plaintiffs' allegations similar to cases in which the Supreme Court has relaxed the standard for third-party standing on the ground that the plaintiffs themselves were directly regulated. *See Kowalski*, 543 U.S. at 130. In those cases, the plaintiffs themselves faced

penalties or losses for violations of the challenged regulations. *See, e.g.*, *Craig v. Boren*, 429 U.S. 190, 193 (1976) (sellers could be subject to sanctions); *Griswold v. Connecticut*, 381 U.S. 479, 481 (1965) (physicians were subject to criminal prosecution). That is not the case here. It is drug sponsors, not plaintiffs, who bear the responsibility for ensuring compliance with the ETASU requirements. *See* 21 U.S.C. § 355-1(g). Plaintiffs face no direct penalties stemming from an enforcement action by FDA, so this is not a situation where "enforcement of the challenged restriction *against the litigant* would result indirectly in the violation of third parties' rights." *Kowalski*, 543 U.S. at 130 (quoting *Warth v. Seldin*, 422 U.S. 490, 510 (1975)).

Even putting that fact aside, the Supreme Court has never relaxed the standard for third-party standing when the interests of the plaintiffs and the rights-bearers are "potentially in conflict." *See Elk Grove Unified Sch. Dist. v. Newdow*, 542 U.S. 1, 15 (2004). And here, at least in areas of the country where the risk of contracting COVID-19 is low, plaintiffs' interest in greater flexibility to provide prescriptions remotely despite FDA's concerns about patient safety is at least potentially in conflict with the interests of patients in seeking safe, reliable care. Accordingly, the standard for third-party standing applies here with its ordinary rigor, and plaintiffs have failed to meet it.[2]

3. Plaintiff SisterSong Lacks Organizational Standing

The only plaintiff-organization purporting to count patients among its membership is plaintiff SisterSong Women of Color Reproductive Justice Collective. Compl. ¶ 28. That

[2] At the very least, this Court should defer considering plaintiffs' request for a preliminary injunction pending the Supreme Court's decision in *June Medical Services v. Gee*, Nos. 18-323 & 18-1460. The Court's determination in that case regarding whether abortion providers may assert third-party standing on behalf of their patients will be of obvious relevance in deciding whether plaintiffs may assert standing here.

organization, however, cannot establish standing because it fails to identify a specific member who is likely to request Mifeprex. *See Summers v. Earth Island Institute*, 555 U.S. 488, 1152 (2009). The only member that SisterSong identifies is "Serina Floyd, M.D., M.S.P.H., FACOG, . . . a certified mifepristone prescriber." Compl. ¶ 30. As discussed, prescribers in this case are not entitled to assert standing on behalf of their potential patients. Because plaintiffs fail to identify any potential patients who are members of SisterSong, that organization lacks standing.

B. Plaintiffs Are Unlikely to Succeed on Their Due Process Claim

"The fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 874 (1992) (joint opinion). Instead, to establish a due process violation, a plaintiff must show that the law imposes an "undue burden" on abortion access. *Id.*

There is some "uncertainty" regarding how this standard applies in the context of a facial challenge, such as this case. *Richmond Med. Ctr. for Women v. Herring*, 570 F.3d 165, 174 (4th Cir. 2009) (en banc). In *Casey*, the Supreme Court stated that a spousal-notification law poses an undue burden if "in a large fraction of the cases in which [the law] is relevant, it will operate as a substantial obstacle to a woman's choice to undergo an abortion." *Casey*, 505 U.S. at 895. But the Court did not explain whether this standard displaces the general rule that a law is facially unconstitutional only if "no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). In prior cases challenging abortion regulations, the Court had applied the general rule. *See Ohio v. Akron Center for Reproductive Health*, 497 U.S. 502, 514 (1990) (*Akron II*).

Some Fourth Circuit cases have suggested that the general rule continues to apply to facial challenges to abortion regulations post-*Casey*. *See Greenville Women's Clinic v. Bryant*, 222 F.3d 157, 165 (2000); *Manning v. Hunt*, 119 F.3d 254, 268 n.4 (1997). Others have suggested that whether the general rule or *Casey*'s large-faction formulation applies is an open question. *See Herring*, 570 F.3d at 174; *Planned Parenthood of Blue Ridge v. Camblos*, 155 F.3d 352, 381 n.14 (1998) (en banc); *see also Hellerstedt*, 136 S. Ct. at 2343 n.11 (Alito, J., dissenting) (noting that the proper standard remains an "open question").

The proper standard to apply to this facial challenge to the Mifeprex in-person dispensing requirement is the *Salerno* rule. No sound basis exists to carve out an abortion exception to that general rule, which provides a readily administrable standard that preserves proper respect for the separation of powers. *See Bryant*, 222 F.3d at 165. Nor is there any basis in precedent to employ *Casey*'s large-fraction formulation, as *Casey* did not expressly depart from *Salerno* or *Akron II*, and the Supreme Court has never held that *Casey* displaces the *Salerno* rule. Under either standard, however, plaintiffs are unlikely to establish a due process violation.

1. Plaintiffs Are Unlikely to Establish that the In-Person Dispensing Requirement Is Invalid in All Circumstances

As explained, under the usual rule that applies to facial challenges, a law is unconstitutional only if "no set of circumstances exists under which the Act would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987). Here, plaintiffs have not shown that the in-person dispensing requirement is invalid in *all* circumstances, nor have they even made such an argument. And even if they had made such an argument, it would fail. Mifeprex was not even approved by FDA for use until 2000. Plaintiffs wisely do not contend that FDA was acting unconstitutionally before 2000, or would have violated the Constitution had it declined to approve the drug. And even now, Mifeprex is approved for use only through the tenth week of

pregnancy, *see* Compl. Ex. 1 at 17, meaning that it is not approved for use by many women to obtain a pre-viability abortion. Nothing in the Constitution compels the federal government to make it easier for women to obtain an abortion by approving a particular drug, much less ensure that the dispensing of that drug is left unregulated. Mifeprex's in-person dispensing requirement "leaves a pregnant woman with the same choices as if the Government had chosen not to" approve Mifeprex "at all." *Rust v. Sullivan*, 500 U.S. 173, 202 (1991).

But even if one were to look solely at the effects of the in-person dispensing requirement on access to that one drug, one can readily identify examples in which that requirement would be valid, including in the context of the COVID-19 pandemic. For example, a patient who drives a short distance by herself to a doctor's office to pick up her prescription and who interacts with a single person in the office at a distance of more than six feet clearly has not experienced an undue burden. The in-person dispensing requirement easily satisfies the *Salerno* standard.

2. Plaintiffs Are Unlikely to Establish that the In-Person Dispensing Requirement Is a Substantial Obstacle to a Large Fraction of Patients Seeking An Abortion

The in-person dispensing requirement also satisfies *Casey*'s large-fraction formulation. Under this framework, a law affecting abortion access imposes an undue burden only if it creates a "substantial obstacle" to obtaining an abortion "in a large fraction of the cases in which [the law] is relevant." *Casey*, 505 U.S. at 895; *see also Hellerstedt*, 136 S. Ct. at 2309. The fact that a law "makes it 'more difficult or more expensive to procure an abortion'" is not enough to meet this threshold standard. *Bryant*, 222 F.3d at 169-70 (quoting *Casey*, 505 U.S. at 874). Rather, as the Fourth Circuit has emphasized, "the focus must be aimed more directly at *the ability to make a decision* to have an abortion." *Id.* (emphasis in original). Where "there is no evidence that the

ability of any woman to obtain an abortion or to decide to obtain an abortion would be frustrated by the[] particularized costs" associated with a law, there is no undue burden. *Id.* at 171.

Notably, plaintiffs essentially ignore the substantial-obstacle requirement—the term appears only once in their brief, *see* PI Br. at 24—and instead apply a pure balancing test that the controlling opinion in *Casey* declined to adopt. *See Casey*, 505 U.S. at 877 (plurality opinion) (adopting a threshold substantial-obstacle requirement). Case law following *Casey* makes clear, however, that the substantial-obstacle requirement is a prerequisite to relief. *See, e.g.*, *Hellerstedt*, 136 S. Ct. at 2300, 2309, 2312, 2316, 2318 (repeatedly referring to *Casey*'s substantial-obstacle requirement, including in key holdings); *Mazurek v. Armstrong*, 520 U.S. 968, 972-73 (1997) (per curiam) (upholding a law that only physicians could perform abortions because there was "insufficient evidence" the law posed a "substantial obstacle"). Plaintiffs are unlikely to satisfy the substantial-obstacle requirement for multiple reasons.

To begin, the Mifeprex REMS applies only to one type of procedure—medication abortion initiated using Mifeprex or its generic. It does not restrict, regulate, or in any way impact any other type of procedure. As the Supreme Court has made clear, a law "does not construct a substantial obstacle to the abortion right" where it allows other "commonly used and generally accepted method[s]." *Gonzales v. Carhart*, 550 U.S. 124, 165 (2007). Plaintiffs provide no evidence that Mifeprex is the only commonly used and generally accepted method of abortion, nor could they. Millions of patients obtained abortions before FDA approved Mifeprex in 2000, and millions more have obtained abortions through other methods in the years since. *See* CDC, Data and Statistics, https://www.cdc.gov/reproductivehealth/data_stats /index.htm (last accessed June 9, 2020). In addition, Mifeprex is approved for use only for the first ten weeks of pregnancy, *see* Compl. Ex. 1 at 17, so the REMS does not operate as a

restriction *at all* after that point. There is no constitutional "right to the abortion method of the woman's (or the physician's) choice." *In re Abbott*, 956 F.3d 696, 720 (5th Cir. 2020) (*Abbott II*). Rather, the right protects "*the ability to make a decision* to have an abortion." *Bryant*, 222 F.3d at 170. Because the Mifeprex REMS affects only one type of abortion procedure, and leaves other commonly used methods untouched, plaintiffs cannot show that the in-person dispensing requirement operates as a substantial obstacle for a large fraction of women seeking an abortion during the pandemic.

Moreover, even under the incorrect view that the right to abortion includes the right to a particular type of procedure—here, medication abortion—the in-person dispensing requirement still does not constitute a substantial obstacle. Plaintiffs claim that the in-person dispensing requirement burdens access to medication abortion by (1) "forcing unnecessary travel and in-person interactions during a pandemic;" (2) "forcing patients to take on increased medical risk"; (3) "exacerbat[ing] the burdens that many abortion patients already face[] in attempting to pay for and arrange transportation and childcare"; and (4) "forc[ing] some patients to delay their care." PI Br. at 26-28. But even assuming the in-person dispensing requirement incidentally affects access to medication abortion, plaintiffs are unlikely to establish that this requirement is a substantial obstacle to a large fraction of women seeking medication abortion.

Since 2000, millions of women have taken Mifeprex for medication abortion, *see* Defs.' Ex. 16 at 0422, indicating that the in-person dispensing requirement has *not* been a substantial obstacle. Since Mifeprex's approval, moreover, FDA has approved modifications to the REMS that have lessened restrictions on Mifeprex by allowing certain nonphysicians to prescribe the drug (if they meet the certification requirements), allowing Mifeprex to be taken outside of a

prescriber's office, and reducing restrictions on follow-up visits. Defs.' Ex. 16 at 0414-38; Ex.17 at 728.

COVID-19 does not transform the in-person dispensing requirement into a "substantial obstacle" to medication abortion. The requirement obliges patients seeking a medication abortion to make a one-time visit to a doctor, hospital, or clinic. Any slight increase in "medical risk" associated with a one-time visit to a medical professional, PI Br. at 27, is at most an "incidental effect" of the in-person requirement, *Bryant*, 222 F.3d at 166. Indeed, the same or similar "risk" of exposure to COVID-19 arises *whenever* a patient travels outside the home, whether to go to the store, the park, or any other location. Plaintiffs provide no evidence that the risk of exposure to COVID-19 at an abortion clinic or prescriber's office is any higher than anywhere else a person might travel on a routine basis, particularly for women under the age of 50 (the relevant demographic). That plaintiffs waited over two months after the pandemic was declared to file suit, *see* World Health Organization, WHO Timeline—COVID-19, https://www.who.int/news-room/detail/27-04-2020-who-timeline---covid-19 (last accessed June 9, 2020) (stating that the WHO declared COVID-19 a pandemic on March 11, 2020), additionally undermines their claim that the "risks" associated with COVID-19 warrant a court order immediately enjoining enforcement of the in-person dispensing requirement. Plaintiffs also fail to note that enjoining enforcement of the requirement may increase delays in picking up the prescription (or receiving it by mail) and initiating an abortion, *see* Defs.' Ex. 14 at 0356-57, leading in turn to increased risk of bleeding requiring hospitalization that places the patient and others at increased risk.

Furthermore, CDC has made clear that there are numerous steps patients and medical professionals can take to ensure patient safety in light of COVID-19. These include asking

patients about symptoms before visits, "plac[ing] chairs 3–6 feet apart, when possible," using face masks, and frequently disinfecting surfaces. CDC, *Prepare your practice for COVID-19,* https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-resources.html (last accessed June 9, 2020). Plaintiffs provide no evidence that abortion clinics and prescribers' offices are unable to follow this guidance. Instead, plaintiffs repeatedly emphasize that CDC recommended, in March 2020, during the height of the pandemic, that "[l]everaging telemedicine whenever possible is the best way to protect patients and staff from COVID-19." PI Br. at 1, 12, 29. But CDC has *never* advised that patients should avoid in-person services that have been deemed necessary by FDA, such as those at issue here. Indeed, the very guidance on which plaintiffs rely to argue that any required travel outside the home is constitutionally impermissible focuses almost entirely on how healthcare providers can mitigate the risk of seeing patients in person during the pandemic. *See id.*

That the in-person dispensing requirement may entail additional travel and childcare expenses as compared to obtaining the drug through, for example, the mail, PI Br. at 27, also does not make the REMS a "substantial obstacle" to obtaining an abortion. As the Fourth Circuit has explained, so long as a regulation is "not designed to strike at the [abortion] right itself—the fact that it also has the incidental effect of making it more difficult or more expensive to procure an abortion cannot be enough to invalidate it." *Bryant*, 222 F.3d at 166. "Only when the increased cost of abortion is prohibitive, essentially depriving women of the choice to have an abortion, has the Court invalidated regulations because they impose financial burdens." *Bryant*, 222 F.3d at 167; *see also id.* at 171 (finding no undue burden where regulation had potential to increase cost of abortion by $75 and require some patients to travel an additional 70 miles). Even if the plaintiffs could show some costs associated with the in-person requirement, they

have not shown that those costs are "prohibitive" for some patients, let alone a "large fraction" of patients—particularly when the alternative is surgical abortions that were the only option before FDA approved Mifeprex in 2000.

Plaintiffs' allegation that some patients who wish to obtain a medication abortion may "delay their care" because of the in-person dispensing requirement, PI Br. at 28, also does not establish that the requirement is a "substantial obstacle" to obtaining an abortion. Plaintiffs fail to provide any evidence regarding how many patients may be forced to delay care because of the requirement. And it is far from clear that enjoining FDA from enforcing the requirement would actually reduce delays in the first place, as some patients would instead wait for the drug to arrive in the mail, or would visit pharmacies that may not have it in stock (particularly in the near future, since the drug is not currently available for dispensing in retail pharmacies) or that may decide not to stock it. In any event, the mere fact that a law may cause some delay in obtaining an abortion does not mean that the law constitutes a substantial obstacle. *See Casey*, 505 U.S. at 886 (upholding mandatory 24-hour waiting period, which lower court found would often cause "a delay of much more than a day").

Plaintiffs further assert that because of the in-person dispensing requirement, "some patients will be delayed to the point when they cannot obtain a medication abortion at all, and will instead have to incur the greater exposure risks associated with an in-office [surgical] abortion." PI Br. at 23. But again, the same could be said about FDA's decision not to approve use of Mifeprex after the tenth week of pregnancy—a decision plaintiffs evidently find constitutionally acceptable. To the extent delays are caused by difficulties lining up transportation or arranging childcare, *see* PI Br. at 27, they are also not the government's creation and provide no basis for setting aside the in-person dispensing requirement. *See Harris*

v. McRae, 448 U.S. 297, 316 (1980) ("[A]lthough government may not place obstacles in the path of a women's exercise of her freedom of choice, it need not remove those not of its own creation."). And in any event, "an abortion regulation should not be invalidated on a facial challenge based on a worstcase analysis that may never occur." *Manning*, 119 F.3d at 268 (internal quotation marks omitted). Plaintiffs provide no evidence regarding how many patients will be unable to obtain a medication abortion because of delays caused by the in-person dispensing requirement, nor do they identify any instances of patients who were unable to obtain a medication abortion because of such delays.

Recent court decisions considering the undue burden standard in light of COVID-19 support the conclusion that the in-person dispensing requirement is not a substantial obstacle to obtaining an abortion. In *In re Rutledge*, 956 F.3d 1018 (8th Cir. 2020), for example, the Eighth Circuit held that an Arkansas order temporarily suspending non-essential medical procedures in light of COVID-19 was not a "substantial obstacle" to obtaining an abortion in the absence of any findings that the order would prevent patients from obtaining an abortion at a later date or require them to undergo a more invasive procedure. *See id.* at 1032. As explained, plaintiffs have submitted no evidence that the in-person dispensing requirement has delayed, or will delay, patients' ability to obtain medication abortions to the point that patients must undergo more invasive procedures or forfeit the ability to obtain an abortion altogether. Still less is there evidence that the requirement has done so for a "large fraction" of patients. And in *Abbott II*, 956 F.3d at 724, the Fifth Circuit vacated a district court injunction prohibiting application of a Texas suspension order to non-essential abortion procedures on the ground that the district court improperly treated the order as a "categorical ban" on non-essential abortion procedures rather than a temporary delay. *See id.* at 719 (explaining that no patient would be "pushed beyond the

legal limit" for obtaining an abortion by the Texas order). Likewise here, the in-person dispensing requirement does not "ban" anything. Rather, it merely places conditions on the dispensing of one specific type of abortion drug that FDA was under no constitutional obligation to authorize in the first place.

Notably, the cases that have found undue burdens with regard to orders in other States temporarily suspending non-essential medical procedures in light of COVID-19 have done so largely out of concern that such orders may prevent patients from obtaining an abortion at a later date or require patients to undergo a lengthier, more complex abortion procedure once the temporary suspension expires. *See Adams & Boyle, P.C. v. Slattery*, 956 F.3d 913, 929-30 (6th Cir. 2020) (enjoining Tennessee order as applied to patients who will lose the ability to obtain an abortion because of the order or who will have to undergo a more invasive procedure); *Robinson v. Att'y Gen.*, 957 F.3d 1171, 1181, 1183 (11th Cir. 2020) (holding that district court did not err in finding likely undue burden where Alabama order could "render abortions functionally unavailable for at least some women" and emphasizing that injunction allowed state to delay abortions that could safely be postponed); *S. Wind Women's Center LLC v. Stitt*, No. 20-cv-277, 2020 WL 1932900, at *8 (W.D. Okla. Apr. 20, 2020) (approving temporary delay of surgical abortions pursuant to Oklahoma order "so long as the pregnant patient would remain able to lawfully obtain an abortion upon cessation of the Executive Orders"); *Pre-Term Cleveland v. Att'y Gen. of Ohio*, No. 1:19-cv-930, 2020 WL 1957173, at *12-14 (S.D. Ohio Apr. 23, 2020) (focusing on challenges associated with delaying abortions until the "viability limit," when more complicated procedures are required).

Plaintiffs have offered no evidence that the Mifeprex in-person dispensing requirement will prevent patients from obtaining an abortion or will force them to undergo a more invasive

procedure. Indeed, it is hard to understand how they could do so, given that an in-person visit to pick up the drug could be accomplished in less time than waiting for a delivery by mail or for a retail pharmacy to get the drug in stock.[3] In the absence of any actual evidence that the in-person dispensing requirement causes delays that require patients to undergo more invasive procedures or that prevent patients from obtaining abortions altogether, these cases do not support plaintiffs' argument. In addition, the cases all involve a temporary ban on non-essential abortion procedures, whereas the in-person dispensing requirement does not ban anything.

In all events, as noted above, even if the in-person dispensing requirement did have the effect of delaying some patients from obtaining a medication abortion to the point that they would have to obtain a different type of abortion—and plaintiffs provide no evidence that this is the case—that still would not constitute a substantial obstacle to obtaining an abortion, because as explained, there is no constitutional right to a medication abortion in the first place. *See supra* at 14-15. Medication abortion through Mifeprex has only been available in the United States since 2000, has never been available for all pre-viability abortions, and has always been subject to the in-person dispensing requirement. For all of these reasons, the requirement easily passes muster under the *Casey* large-fraction formulation.

3. Plaintiffs Are Unlikely to Establish that Any Burdens the In-Person Dispensing Requirement Imposes Outweigh Its Substantial Benefits

[3] Plaintiffs' criticism that Mifeprex is not available in retail pharmacies, Compl. ¶ 60, is also a red herring because plaintiffs do not challenge the Mifeprex REMS's separate directive that distribution be limited to "clinics, medical offices and hospitals," *see* Defs.' Ex. 21 at 2-3. And even if they did, patients would likely have a hard time finding a pharmacy that could quickly stock Mifeprex given that the drug is not currently available in such settings. Retail pharmacies are also likely in many instances to be riskier locations to pick up Mifeprex than a clinic or doctor's office, given higher foot traffic and a lower likelihood of enforcing social distancing and face-mask requirements than clinical settings.

Because plaintiffs are unlikely to establish that the in-person requirement constitutes a substantial obstacle to a large fraction of patients seeking an abortion, the Court need not consider the requirement's benefits. But if the Court nonetheless does so, it should conclude that plaintiffs are unlikely to succeed in establishing that any incidental burdens the requirement imposes outweigh its substantial benefits.

To start, FDA has determined that the in-person dispensing requirement is necessary to mitigate serious risks associated with the drug's use. *See supra* at 4-6. This determination, which lies squarely within FDA's area of special expertise and which FDA based on dozens of clinical trials and agency reviews, *see* Defs.' Exs. 11, 14, 16, is entitled to significant deference. *See, e.g.*, *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009) (affording a "high level of deference" to FDA's "scientific judgment within its area of expertise"); *Ohio Valley Envmtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 205 (4th Cir. 2009) ("When an agency is called upon to make complex predictions within its area of special expertise, a reviewing court must be at its most deferential.").

Among other things, the in-person dispensing requirement ensures that Mifeprex is dispensed "under the direct supervision of a certified prescriber," Defs.' Ex. 16 at 0436; Ex. 18 at 0681, thus allowing for counseling about the risk of serious patient complications associated with Mifeprex (and what to do if such complications arise) *at the time of dispensing*. Defs.' Ex. 14 at 0356-57. Those risks include serious infection (including sepsis) and sometimes-life-threatening bleeding or incomplete abortion that requires surgical intervention for up to seven out of every 100 patients who take the drug. Compl. Ex. 1 at 17. Dispensing the drug in broader settings, such as through retail or mail-order pharmacies, could also expose patients to unnecessary and increased risks. *See* Defs.' Ex. 14 at 0356. For example, patients might delay picking up their

Mifeprex prescription and initiating an abortion, resulting in increased risk. *See id.* Patients might also have a hard time finding a pharmacy that stocks Mifeprex, or experience delays with mail delivery, resulting in similar delays with potential patient complications. *See id.* Indeed, to the extent patients choose to go to a retail pharmacy rather than order the drug through the mail—a not-unlikely scenario given widespread delays with mail service caused by COVID-19, *see, e.g.*, U.S. Postal Service, USPS Coronavirus Updates: Expected Delivery Changes, https://faq.usps.com/s/article/USPS-Coronavirus-Updates-Expected-Delivery-Changes (last accessed June 9, 2020) (noting that "packages may temporarily require more time to be delivered due to limited transportation availability as a result of the Coronavirus (COVID-19) pandemic")—suspending the in-person dispensing requirement could expose patients to *greater* risk of COVID-19, *see supra* at 21 n.3. The in-person requirement thus carries the substantial benefit of helping ensure patient safety.

Plaintiffs contend that the in-person dispensing requirement "serves no medical purpose" and is "illogical on its face" because patients are allowed to take the drug at home. PI Br. at 24-25. But plaintiffs provide no evidence that Mifeprex would remain safe for patient use in the absence of the in-person dispensing requirement. To the contrary, the evidence that *does* exist shows that Mifeprex's safety profile "ha[s] not substantially changed" since the drug was first approved with the in-person dispensing requirement in place. Defs.' Ex. 18 at 0681. FDA does not approve modifications to a drug's REMS absent an adequate rationale for the changes, including data to support the proposed changes. *See, e.g.*, Defs.' Ex. 10 at 12-13.

The ramifications of plaintiffs' argument are also deeply problematic. According to plaintiffs, because FDA in 2016 eased restrictions on where patients can *take* Mifeprex, FDA is required to also ease restrictions on where patients can *obtain* Mifeprex. But there is no reason

why FDA should be required to ease restrictions on taking and restrictions on obtaining a drug in tandem, particularly where (as here) the sNDA that prompted FDA's review did not request changes to both. Defs.' Ex. 16 at 0414-15. FDA can reasonably ease one restriction while leaving the other in place. There is no reason to subject FDA to the sort of regulatory straitjacket plaintiffs seek to foist upon the agency.

Plaintiffs also argue that the in-person dispensing requirement serves no purpose because, they claim, serious complications associated with the use of Mifeprex are "extremely rare" and do not "manifest until hours or days later." PI Br. at 26. But according to the underlying safety data that FDA evaluated in approving Mifeprex, approximately "2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop the bleeding." Compl. Ex. 1 at 17. Plaintiffs' argument that complications may not manifest until later also overlooks that the requirement ensures that (1) at the time of dispensing, the patient receives counseling about the risk of serious patient complications associated with Mifeprex and what to do should they arise; and (2) the patient does not delay picking up their prescription—or the prescription is not delayed in the mail—and initiating an abortion. Plaintiffs also provide no evidence that telemedicine would accomplish these goals as effectively as an in-person consultation with a certified prescriber.

Plaintiffs' reliance on the Supreme Court's decision in *Hellerstedt*, *see* PI Br. at 26-28, is misplaced. In *Hellerstedt*, the Court concluded that many abortion clinics had been forced to close as a result of the challenged law—creating a "substantial obstacle" to obtaining an abortion for a "large fraction" of Texas women seeking one—and that there was no record evidence showing the law "advanced Texas' legitimate interest in protecting women's health." *Hellerstedt*, 136 S. Ct. at 2311, 2316, 2320. Here, by contrast, there is no evidence that the in-

person dispensing requirement imposes such burdens on abortion access, and FDA has determined, based on extensive clinical reviews, that the requirement is necessary to ensure patient safety. *See, e.g.*, Defs.' Ex. 14 at 0344. Plaintiffs' other cases are similarly off-point. *See, e.g.*, *Planned Parenthood Ariz., Inc. v. Humble*, 753 F.3d 905, 915-16 (9th Cir. 2014) (striking down Arizona law that banned medication abortions for a "significant number of women" and was "wholly unnecessary as a matter of women's health") (internal quotation marks omitted); *W. Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1317, 1324 (11th Cir. 2018) (enjoining Alabama law that banned the "most commonly used method" for second-trimester abortions and required women to seek alternative procedures that were not "safe, effective, [or] available"); *Planned Parenthood of Wisc. v. Schimel*, 806 F.3d 908, 918, 920 (7th Cir. 2015) (enjoining Wisconsin law where evidence supporting law's benefits was "nonexistent" and law would require some women to undergo riskier procedures and prevent others from obtaining an abortion altogether).

Two additional factors weigh strongly against the conclusion that plaintiffs are likely to succeed in establishing a due process violation. *First*, as plaintiffs repeatedly emphasize (indeed, it is the underpinning of their entire suit), the Nation is in the midst of a public health emergency. But the "Constitution principally entrusts the safety and the health of the people" to officials who must "act in areas fraught with medical and scientific uncertainties," and who therefore, as a general matter, "should not be subject to second-guessing by an unelected federal judiciary, which lacks the background, competence, and expertise to assess public health." *S. Bay United Pentecostal Church v. Newsom*, No. 19A1044, 2020 WL 2813056, at *1 (U.S. May 29, 2020) (Roberts, C.J., concurring in denial of application for injunctive relief) (internal quotation marks omitted). Plaintiffs invite the Court to "second-guess the wisdom or efficacy" of the in-person

dispensing requirement in light of COVID-19. *In re Abbott*, 954 F.3d 772, 785 (5th Cir. 2020) (*Abbott I*). But "'[i]t is no part of the function of a court' to decide which measures are 'likely to be the most effective for the protection of the public against disease.'" *Id.* at 778 (quoting *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905)); *see also Rutledge*, 956 F.3d at 1029 (warning against "encroach[ing] upon the State's policy determinations in how best to combat COVID-19"). The proper course of action here—particularly in light of the serious public health concerns associated with the current pandemic—is for the Court to defer to FDA's medical judgment on the Mifeprex REMS.

Second, plaintiffs ask the Court to do something that no court has *ever* done—apply *Casey*'s undue burden framework to strike down measures FDA put in place as part of a drug approval process that FDA determined were "necessary" to ensure patient health and safety. Especially in an area quintessentially within FDA's expert scientific judgment—evaluating a drug's risks to determine the appropriate restrictions necessary to ensure safe use—the Court should not supplant the agency's judgment, even in the context of a constitutional question. *See, e.g.*, *Abigail Alliance v. Eschenbach*, 495 F.3d 695, 709 (D.C. Cir. 2007) (expressing skepticism at "a constitutional right to override the collective judgment of the scientific and medical communities expressed through the FDA's clinical testing process"); *All. for Nat. Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 12 (D.D.C. 2011) ("While the Court is obligated to conduct an independent review of the record and must do so without reliance on the FDA's determinations as to constitutional questions, it must also give deference to an agency's assessment of scientific or technical data within its area of expertise.") (internal quotation marks and citation omitted)).

C. Plaintiffs Are Unlikely To Succeed on Their Equal Protection Claim

Plaintiffs contend that the in-person dispensing requirement denies equal protection because the requirement allegedly treats Mifeprex prescribers differently from prescribers of

other drugs and because the requirement allegedly lacks any rational justification. PI Br. at 28-32. Under Fourth Circuit precedent, equal protection challenges to laws that regulate abortion providers and that do not place an undue burden on the right to an abortion are subject to rational basis review. *See Bryant*, 222 F.3d at 173. A law will be upheld under this standard "so long as it bears a rational relation to some legitimate end." *Vacco v. Quill*, 521 U.S. 793, 799 (1997).

Plaintiffs identify two ways in which FDA has allegedly treated Mifeprex prescribers differently from "[s]imilarly [s]ituated" prescribers of other drugs. PI Br. 29. *First*, HHS has waived the requirement that prescribers perform in-person patient evaluations before writing prescriptions for numerous controlled substances, including opioids. *Id.* at 29-30. But the in-person dispensing requirement does not require an in-person evaluation before *prescribing*. Rather, it requires that Mifeprex be picked up in person so that the prescriber has an opportunity to review (or re-review) the risks associated with the drug at the time of *dispensing*. *See supra* at 5-6. It also helps ensure that the patient does not delay picking up their prescription and initiating an abortion. *See id.* Furthermore, the decision to waive the pre-prescription in-person evaluation requirement for certain controlled substances was not even made by FDA—it was made by DEA and HHS Secretary Azar. *See* COVID-19 Information Page, Telemedicine, U.S. Drug Enf't Admin., https://www.deadiversion.usdoj.gov/coronavirus.html#TELE (last visited June 9, 2020).

Second, plaintiffs point out that FDA has exercised enforcement discretion for certain REMS requirements during the pandemic that may require in-person hospital or doctor's office visits. *See* PI Br. at 27-28. The FDCA sets forth six ETASU that FDA may include as part of a REMS strategy to mitigate patient risk. *See* 21 U.S.C. § 355-1(f)(3). These include: (A) requiring prescribers to have "particular training or experience" or be "specially certified"; (B)

requiring "pharmacies, practitioners, or health care settings that dispense the drug" to be "specially certified"; (C) requiring that "the drug be dispensed to patients only in certain health care settings, such as hospitals"; (D) requiring that "the drug be dispensed only to patients with evidence or other documentation of safe-use conditions, such as laboratory test results"; (E) requiring "each patient using the drug [to] be subject to certain monitoring"; and (F) requiring "each patient using the drug [to] be enrolled in a registry." *Id.* In March, FDA announced that, during the COVID-19 public health emergency, it would exercise enforcement discretion for REMS requirements pertaining to ETASU D (documentation of safe-use conditions) and ETASU E (patient monitoring) insofar as those requirements apply to laboratory testing and imaging studies. U.S. Food & Drug Admin., Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals (Mar. 2020), https://www.fda.gov/media/136317/download.

Plaintiffs argue that FDA's decision to exercise enforcement discretion for ETASU D and E as applied to laboratory tests and imaging studies during the pandemic means FDA is required to exercise enforcement discretion with respect to the in-person dispensing requirement, too. But the in-person dispensing requirement does not even derive from either of those ETASU. Rather, it derives from ETASU C (in-person dispensing). FDA's decision to (partially) exercise enforcement discretion for *some* ETASU for some drugs does not require it to exercise enforcement discretion for *other* ETASU for completely different drugs. Furthermore, as Plaintiffs concede, *see* Bryant Decl. ¶ 58, there are over a dozen other drugs subject to an in-person dispensing requirement. The relevant point of comparison for equal protection analysis, therefore, is not laboratory tests and MRIs, but other drugs with the exact same requirement.

In any event, it was not irrational for FDA to announce an intent to exercise enforcement discretion with respect to certain REMS requirements but not others. As explained, when FDA approved Mifeprex, it determined that the in-person dispensing requirement was necessary to ensure the drug's safe use, and Mifeprex's safety profile "ha[s] not substantially changed" in the intervening years. Defs.' Exs. 11, 18. The pandemic does not change either of these facts. That various agencies within HHS have taken steps to encourage telemedicine, *see* PI Br. at 29-30, also does not establish an equal protection violation. None of those agencies has advised patients to avoid in-person services that FDA has determined are necessary to mitigate risk and protect patient safety.

Plaintiffs' assertion that there is no "[r]ational [j]ustification" for the in-person dispensing requirement, PI Br. at 30, is equally unpersuasive. As explained, the requirement ensures that prescribers have an opportunity to provide counseling about the risks associated with the drug's use at the time of dispensing and also helps ensure that patients do not delay picking up their prescription and initiating an abortion. *See supra* at 5-6. In the midst of a pandemic, a doctor's office is also likely a safer location to pick up a drug than a heavily trafficked retail pharmacy, and is also a more reliable source for prescriptions than mail delivery, which, as noted, in many places has been delayed, and some pharmacies, which may opt not to stock the drug. Plaintiffs' further assertion that other "incidental" aspects of the in-person dispensing requirement "add no medical benefit," PI Br. at 31-32, is also wrong. Requiring the patient to sign the Patient Agreement Form in the presence of the prescriber ensures that the prescriber has an opportunity to review the form with the patient at the time of signing; requiring the prescriber to provide the patient a copy gives the patient a copy to reference; and requiring the prescriber to record the

serial number of the drug ensures that the prescriber is accountable for the pills that the prescriber dispenses.

Nor do comparisons with another mifepristone product called Korlym establish that FDA lacks a rational justification for the in-person dispensing requirement. PI Br. at 31. Korlym, which is used to treat a rare and sometimes fatal disease called Cushing's syndrome, has an entirely different use and patient population than Mifeprex. *See* Defs.' Exs. 22 at 0269; Ex. 23 at 0294; Ex. 24 at 0328. In fact, Korlym is actually *contraindicated* for patients who are pregnant. *See* Defs.' Ex. 22 at 0269, 0271. That FDA determined an in-person dispensing requirement was unnecessary for Korlym given that drug's particular indication and patient population, Defs.' Ex. 23 at 0294, does not make Mifeprex's in-person dispensing requirement irrational.

In all events, FDA has determined, in the exercise of its medical and scientific expertise, that the in-person dispensing requirement is necessary to ensure safe patient use, and plaintiffs provide no evidence that Mifeprex would remain safe and effective for patient use in the absence of the requirement. Plaintiffs thus are unlikely to succeed in establishing that the in-person dispensing requirement violates equal protection.

II. Plaintiffs Have Not Established That They Are Likely to Suffer Irreparable Harm in the Absence of Preliminary Relief

Plaintiffs fail to establish that they will experience irreparable harm in the absence of a preliminary injunction. Plaintiffs first argue that they will suffer irreparable harm because the in-person dispensing requirement is unconstitutional. But as discussed, making a one-time visit to a medical professional for one particular drug is not a "substantial obstacle" to obtaining an abortion. *See Casey*, 505 U.S. at 877.

Plaintiffs next argue that the in-person dispensing requirement will cause irreparable harm because it "exposes Plaintiffs' members, their patients, and their families to increased risk

of life-threatening disease." PI Br. at 33. To prevail, however, plaintiffs must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Resources Def Council, Inc.*, 555 U.S. 7, 22 (2008). A mere "possibility of irreparable harm" is insufficient to warrant a preliminary injunction. *Id.*

Plaintiffs' alleged harm here is premised largely on speculation, as it requires a series of attenuated events to transpire before an injury is actually suffered. *See supra* at 7-9. That is insufficient to show Article III standing, much less irreparable harm. *See Aslanturk v. Hott*, No. 1:20-cv-00433, 2020 WL 2465663, at *14 (E.D. Va. May 8, 2020) (mere risk of exposure to COVID-19 insufficient to show irreparable harm); *Toure v. Hott*, No. 1:20-cv-395, 2020 WL 2092639, at *13–14 (E.D. Va. Apr. 29, 2020) (same).

Plaintiffs' final argument, that FDA may not "constrain[] Plaintiffs and their members from exercising their clinical judgment," is a nonstarter. PI Br. at 33. This argument has nothing specific to do with the pandemic—the supposed basis of plaintiffs' challenge. Furthermore, because "[t]he FDA regulates the manufacture, sale, and labeling of prescription drugs under a complex statutory scheme," *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 404 (2012), virtually *every* regulation promulgated by FDA "constrains" healthcare providers' ability to prescribe medication to some degree. Simply alleging that FDA regulates the use of a drug is insufficient to demonstrate irreparable harm.

III. The Balance of Equities and Public Interest Favor Upholding FDA's Expert Judgment that the In-Person Dispensing Requirement Is Necessary to Protect Patient Safety

The balance of equities and public interest factors "merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). There is a strong public interest in ensuring the safety and efficacy of drugs approved for patient use. *See, e.g., United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012) (noting "substantial" government interest in "drug

safety and public health"). As explained, use of Mifeprex carries potentially severe and even life-threatening risks to the patient, and up to seven percent of patients who take the drug will experience complications that require surgical intervention. Compl. Ex. 1 at 17. The in-person dispensing requirement furthers the public interest in ensuring safe patient use by affording patients the opportunity for counseling about the serious risks associated with use of Mifeprex at the time they pick up the drug and by reducing delays that may occur from filling a prescription at a retail pharmacy or through a mail-order service. *See supra* at 5-6. Although plaintiffs may disagree with FDA's expert judgment that the in-person dispensing requirement is necessary to assure safe use, "[t]he public has a strong interest in ensuring that the FDA rather [than] individual doctors has the power to decide what drugs meet baseline levels of safety and efficacy." *Abney v. Amgen, Inc.*, 443 F.3d 540, 553 (6th Cir. 2006); *see also Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 30 (1st Cir. 1995) (noting that the FDCA is predicated on the view that "the public interest will best be served by relying" on FDA "to strike the proper balance between reasonably assuring safety and promoting innovation with regard to new [drugs] that have the potential both to enhance and injure human health"). Accordingly, the public interest in this case strongly supports upholding FDA's scientific judgment.

Plaintiffs' claim that the public interest favors overriding FDA's judgment rings hollow. Plaintiffs contend that the in-person dispensing requirement "jeopardizes" the health and safety of patients, prescribers, clinic staff, and family members, but waited more than two months after the pandemic began to bring this suit. The "risks" of making a one-time, in-person visit to a clinic or doctor's office are also no different from the risks associated with any visit to a health care setting. Nor are they substantially different from the "risks" associated with going to the store, picking up food from a restaurant, or engaging in hundreds of other activities that involve

travel outside the home. There is also no constitutional injury threatened by the in-person dispensing requirement. Under such circumstances, the public interest is best served by deferring to the expert judgment of the agency that has been "primarily entrusted" with "vindicat[ing] the public's interest in health and safety" of drugs approved for patient use. *American Home Prods. Corp. v. Johnson & Johnson*, 436 F. Supp. 785, 797 (S.D.N.Y. 1977).

IV. Plaintiffs' Asserted Injury Does Not Warrant Nationwide Relief

Absent a certified class action, a court generally lacks power under Article III to grant relief that goes beyond what is necessary to provide complete redress to the plaintiffs before it. Yet that is precisely what plaintiffs demand here: that this Court enjoin enforcement of the in-person dispensing requirement against "*all* similarly situated mifepristone prescribers; and any other individuals involved in implementing this Court's relief (such as the drug manufacturer or a mail-order pharmacy)." PI Br. at 35 (emphasis added). Plaintiffs cannot provide a justification for such sweeping relief.

To satisfy Article III, a plaintiff must establish standing "separately for each form of relief sought." *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (internal quotation marks omitted). Thus, where plaintiffs are not themselves injured by the application of the challenged policy to third parties, "[they] lack standing to seek—and the district court therefore lacks authority to grant—relief that benefits third parties." *McKenzie v. City of Chicago*, 118 F.3d 552, 555 (7th Cir. 1997); *cf. Gill v. Whitford*, 138 S. Ct. 1916, 1920 (2018) (proper remedy for challenge to gerrymandering limited to boundaries of individual's own district).

Even apart from Article III's constraints, equity demands that injunctions should "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). The Fourth Circuit and other

courts have routinely enforced this basic principle. *See, e.g.*, *Virginia Society for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001), *overruled on other grounds by The Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544 (4th Cir. 2012) (holding that injunction covering only the plaintiff "adequately protect[ed] it from the feared prosecution" and that "[p]reventing the [agency] from enforcing [the regulation] against other parties in other circuits [did] not provide any additional relief to [the plaintiff].").

Equitable principles reinforce this rule. The availability of non-party injunctions without class certification creates an inequitable "asymmetr[y]," whereby non-parties can claim the benefit of a favorable ruling but are not bound by a loss. *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring). Nationwide injunctions also depart from the historical practice of "providing equitable relief only to parties," *Trump v. Hawaii*, 138 S. Ct. 2392, 2427-28 (2018) (Thomas, J., concurring), because they extend relief to individuals who are not "plaintiff[s] in th[e] lawsuit, and hence were not the proper object of th[e court's] remediation," *Lewis v. Casey*, 518 U.S. 343, 358 (1996).

Plaintiffs' request for a sweeping nationwide injunction disregards these principles. Plaintiffs argue that an injunction extending to "all similarly situated mifepristone prescribers" is "proper" because "a patient's ability to avoid unnecessary viral exposure when obtaining abortion or miscarriage care should not turn on their clinician's professional membership affiliations." PI Br. at 35. But plaintiffs are not in a position to speak on behalf of "all similarly situated mifepristone prescribers," let alone all of the unidentified potential patients of all their unidentified members—some of whom may well agree with the in-person dispensing requirement—because plaintiffs never sought to certify a class. *See Virginia Soc'y for Human Life*, 263 F.3d at 393.

Seeking to impose sweeping, nationwide relief is especially inappropriate in this case given the varying levels of risk posed by COVID-19 in different places and among different age groups. *See* CDC, *Cases in the U.S.*, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html (last accessed June 9, 2020); CDC, *People Who are at Higher Risk for Severe Illness*, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-higher-risk.html (last accessed June 9, 2020). Yet a blanket nationwide injunction would apply to all prescribers and patients indiscriminately without taking into account meaningful differences in geography and health.

In attempting to justify nationwide relief, plaintiffs rely on the Fourth Circuit's decision in *Roe v. Department of Defense*, 947 F.3d 207 (4th Cir. 2020), which involved a challenge to the Air Force's policy of removing HIV-positive airmen from service. *See* PI Br. at 42. In that case, however, the court expressly emphasized the limited nature of the relief it upheld. *See, e.g.*, *id.* at 233. *Roe* also proceeded via the Administrative Procedure Act (APA). Although nationwide relief is neither authorized nor required under the APA, *see, e.g.*, *Virginia Soc'y for Human Life, Inc.*, 263 F.3d at 394, courts have sometimes (incorrectly) read that statute to justify nationwide relief. Plaintiffs, however, do not bring an APA claim in this case. Because plaintiffs cannot justify their requested nationwide relief, this Court should refuse plaintiffs' demand for a nationwide injunction.

CONCLUSION

For the reasons discussed above, the Court should deny plaintiffs' motion for a preliminary injunction. At a minimum, any injunction should be no broader than necessary to redress any concrete, cognizable injuries actually established by plaintiffs.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of June 2020, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

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